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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,958	08/25/2006	Petra Cirpus	13987-00019-US	9681

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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,958	CIRPUS ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 14-26* is/are pending in the application.

4a) Of the above claim(s) *14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments to the specification and the claims filed August 27, 2009 have been entered.

Claims 1, 6 and 14 are currently amended.

Claims 25 and 26 are newly submitted.

Claims 1-9 and 14-26 are pending.

Claims 1-9, 25 and 26 are examined on the merits.

Election/Restrictions

1. This application contains claims 14-24 drawn to an invention nonelected with traverse in the reply filed on August 27, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

2. Claim 1 is objected to for the recitation that the omega-3 desaturase of the method is for desaturation of C20 or C22 fatty acids, while the formula recited in the claim encompasses fatty acids that are from 9 carbons to 31 carbons. It is not understood how the process that requires use of a desaturase that acts on 20 or 22 carbon fatty acids would be a process that produces fatty acids that range from 9 carbons to 31 carbons. Clarification is requested.

3. Claim 26 is objected to for the recitation of the singular "fatty acid" at the end of the claim, where it should read the plural "fatty acids".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a process to produce fatty acids by introducing into an organism an omega-3 desaturase that is capable of desaturating C20 or C22 fatty acids, or that is capable of desaturating all of C18, C20 and C22 fatty acids. However, the specification only discloses SEQ ID NO: 1 encoding SEQ ID NO: 2 (Pi-omega3Des) shown to have said activity on C18, C20 and C22 fatty acids when expressed in yeast (see Figure legends at pages 66-67 and Figures, for example). No other sequences having the claimed functional activity have been disclosed, and one sequence is not sufficient to describe the structural characteristics required for the claimed genus of sequences that have omega-3 desaturase activity that is capable of desaturating C20 or C22 fatty acids, or that is capable of desaturating C18, C20 and C22 fatty acids (claim 26).

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." In addition, "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no

further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention". See *University of California v. Eli Lilly and Co.,* 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-9, 25 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/566,944. Although the conflicting claims are not identical, they are not patentably

distinct from each other because claim 3 of Application No. 10/566,944 is drawn to a method of making polyunsaturated fatty acids in an organism by transforming the organism with an omega-3 desaturase coding sequence in combination with other fatty acid biosynthesis genes., which would be obvious in view of the present claims drawn to to a method of making polyunsaturated fatty acids in an organism by transforming the organism with an omega-3 desaturase coding sequence and optionally together with other fatty acid biosynthesis genes

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Applicants' arguments filed August 27, 2009 have been fully considered but they are not persuasive. Applicants state that a terminal disclaimer will be filed if the rejection stands when the claims are in condition for allowance. The Examiner maintains that the rejection is proper and will be maintained until a terminal disclaimer is filed or the co-pending claim is cancelled.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3-9 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Spychalla et al (PNAS USA 94(4): 1142-1147, February 18, 1997 in IDS).

11. The claims are drawn to a method of making polyunsaturated fatty acids (PUFAs) in an organism by transforming the organism with an omega-3 desaturase coding sequence that desaturates C20 or C22 fatty acids, wherein the organism may be a plant, such as Arabidopsis, which is a Brassicaceae, wherein the oil extracted from the plant has the PUFA in a concentration of at least 5% by weight of the total lipid content. It is noted that delta-15 desaturase is another name for omega-3 desaturase.

12. Spychalla et al teach an omega-3 desaturase coding sequence that desaturates C20 and C18 fatty acids transformed into Arabidopsis, wherein the oil extracted from the plant has the PUFA in a concentration of at least 5% by weight of the total lipid content (see the abstract and the paragraph bridging pages 1144-1145, for example), and the substituents of R2 and R3 of claim3 and 4 would be inherent in the same method.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-9, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon (US Patent 6,459,018) taken with Spychalla et al (PNAS USA 94(4): 1142-1147, February 18, 1997 in IDS) and further in view of Browse et al (US Patent 6,884,921).

16. The claims are drawn to a method of making polyunsaturated fatty acids (PUFAs) in an organism by transforming the organism with an omega-3 desaturase coding sequence that desaturates C20 or C22 fatty acids, optionally in combination with other fatty acid biosynthesis genes (claim 2), wherein the organism may be a plant, such as Brassica, wherein the oil extracted from the plant has the PUFA in a concentration of at least 5% by weight of the total lipid content. Claim 26 is drawn to the process wherein the omega-3 desaturase is capable of desaturating C18, C20 and C22 fatty acids. It is noted that delta-15 desaturase is another name for omega-3 desaturase.

17. Knutzon (US Patent 6,459,018) teaches a method of making polyunsaturated fatty acids (PUFAs) in a plant by transforming a Brassica plant with an omega-3 desaturase coding sequence, and further in combination with other fatty acid biosynthesis genes, such as a delta-6 desaturase, wherein the PUFA extracted from the Brassica plant is stearidonic acid (18:4) in a concentration of greater than 7% (see the Detailed Description at paragraphs 40-49 and Table 2).

18. Knutzon et al does not teach an omega-3 desaturase that desaturates C20 or C22 fatty acids.

19. Spychalla et al teach the FAT1 omega-3 desaturase that desaturates C20 or C18 fatty acids transformed into Arabidopsis, wherein the oil extracted from the plant has the PUFA in a

concentration of at least 5% by weight of the total lipid content (see the abstract and the paragraph bridging pages 1144-1145, for example).

20. Browse et al teach that the FAT-1 omega-3 desaturase also desaturates C22 fatty acids.

21. Given the recognition of those of ordinary skill in the art of the value of producing long chain PUFAs in plants by transforming a plant with a desaturase coding sequence and optionally other fatty acid biosynthesis genes, as taught by Knutzon, it would have been obvious to use the process taught by Knutzon and to substitute other known desaturase coding sequences, such as the desaturase coding sequence taught by Spychalla et al, in view of Browse et al, which has been shown to desaturate at least C18, C20 and C22 fatty acids, and the particular composition of the triacylglycerols produced would be the optimization of process parameters.

22. Applicant's arguments filed August 27, 2009 have been fully considered to the extent they pertain to the present rejection, but they are not persuasive. Applicants argue that the amendment of the claims should overcome the rejection given that the Knutzon patent does not teach the new limitation in the claims. The Examiner maintains that the present claims are still anticipated and/or obvious over the prior art for the reasons set forth.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638